4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1010]

Draft Guidance for Industry on Initial Completeness Assessments for Type II Active Pharmaceutical Ingredient Drug Master Files Under the Generic Drug User Fee Amendments of 2012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled "Initial Completeness Assessments for Type II API DMFs Under GDUFA." Under the Generic Drug User Fee Amendments of 2012 (GDUFA), holders of certain drug master files, namely, Type II active pharmaceutical ingredient (API) drug master files (DMFs) that are referenced in generic drug applications, or in amendments or prior approval supplements to these applications, will be required to undergo an initial completeness assessment in accordance with FDA criteria. This guidance is intended to clarify the criteria FDA will use in the initial completeness assessment.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 744B(a)(2)(D)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-42(a)(2)(D)(ii)) (FD&C Act), which was added by GDUFA, Title III, Food and Drug Administration Safety and Innovation Act (Public Law 112-144), states that, on or after October 1, 2012, a Type II API DMF will be deemed available for reference in an abbreviated new drug application (ANDA), ANDA amendment, or ANDA prior approval supplement (PAS), if the

required fee has been paid and if the DMF has not failed an initial completeness assessment "in accordance with criteria to be published by" FDA. Any Type II API DMF intended for reference in a generic drug submission for which the fee is paid will undergo an initial completeness assessment. Section 744B(a)(2)(D)(iii) of the FD&C Act requires FDA to make publicly available on its Web site a list of DMF numbers that correspond to DMFs that have successfully undergone an initial completeness assessment in accordance with criteria to be published by FDA and are available for reference. This list will thus contain DMF numbers for those DMFs for which the fee has been paid and which have successfully undergone the initial completeness assessment. Note that these provisions do not apply to Type II API DMFs that are not intended to be referenced in an ANDA, ANDA amendment, or ANDA PAS.

Fee amounts and the due date for the fee will be announced in a separate Federal Register notice or notices.

For DMFs that fail the initial completeness assessment, FDA will issue a letter notifying the holder of the DMF that the DMF is incomplete and identifying missing elements in the DMF that must be addressed. Once the DMF is amended, FDA will re-evaluate it for completeness. This draft guidance describes the criteria that FDA will use in its initial completeness assessment of Type II API DMFs to be referenced in generic drug submissions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on initial completeness assessments of Type II API DMFs to be referenced in generic drug submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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